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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,834	09/25/2006	Satoshi Amano	27561U	9819
20529	7590	01/11/2008		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER GRANO, ERNESTO ARTURIO	
			ART UNIT 4147	PAPER NUMBER
			MAIL DATE 01/11/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,834	<b>Applicant(s)</b> AMANO ET AL.	
	<b>Examiner</b> ERNESTO A. GRANO	<b>Art Unit</b> 4147	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/28/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

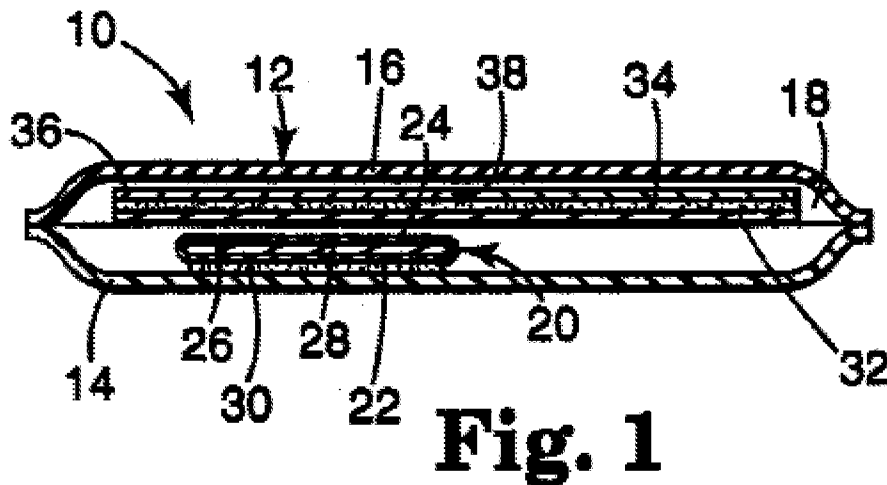
1. The information disclosure statement (IDS) submitted on 07/28/2006 is being considered by the examiner.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US Patent 5,698,217).



4. In re claim 1, with reference to figure 1, Wilking ('217) discloses a patch-containing packaging pouch (10) comprising: a packaging pouch (12); and a patch (38), housed within the packaging pouch (12), in which a pressure-sensitive adhesive layer (34) is formed on one side of a support, wherein the pressure-sensitive adhesive layer (34) is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and a dissolved drug.

5. However, Wilking ('217) fails to disclose bisoprolol or pharmaceutically acceptable salt thereof, and relative humidity inside the packaging pouch at 25°C is maintained at 25% or less.

6. Therefor, It would have been obvious to one having ordinary skill in the art at the time the invention was made to include bisoprolol or pharmaceutically acceptable salt as the dissolved drug and have a relative humidity less then 25% inside the packaging pouch when at 25°C since it was known in the art that a dissolved drug patch needs to be contained within a package of certain relative humidity relevant to the dissolved drug.

7. In re claim 2, with reference to figure 1, Wilking ('217) discloses the claimed invention except for the relative humidity is maintained at 10% or less. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a relative humidity less than 10% inside the packaging pouch since it was known in the art that a dissolved drug patch needs to be contained within a package of certain relative humidity relevant to the dissolved drug and to its storage life.

8. In re claim 3, with reference to figure 1, Wilking ('217) discloses a desiccant (20) that is housed within the packaging pouch (12).

9. In re claim 4, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a substance which physically adsorbs moisture. See col. 3, lines 23-44

10. In re claim 5, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a porous substance. See col. 4, lines 1-14

11. In re claim 6, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a porous substance formed of at least one type of

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material selected from the group comprising a metal oxide, zeolite and a clay mineral.

See col. 4, lines 1-54

12. In re claim 8, with reference to figure 1, Wilking ('217) discloses the packaging pouch (10) has a blocking layer (14) that blocks penetration of moisture. See col. 6, lines 44-47

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US Patent 5,698,217) as applied to claim 1 above, and further in view of Kanios et al. (US Patent 6,905,016).

14. In re claim 7, with reference to figure 1, Wilking ('217) has disclosed a pressure-sensitive adhesive.

15. However, Wilking ('217) fails to disclose a pressure-sensitive adhesive contains at least one type of compound selected from the group comprising a styrene isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer.

16. Kanios et al. ('016). teaches a product packaging system to prevent or control degradation reactions that can result from certain packaging materials and moisture contamination, which includes a pressure-sensitive adhesive made of an acrylic polymer. See col. 7, lines 23-36

17. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pressure-sensitive adhesive of

Wilking ('217) to include an acrylic polymer pressure-sensitive adhesive as taught by Kanios et al. ('016) in order to use an adhesive that will not have a reaction with certain drugs.

18. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US Patent 5,698,217) as applied to claim 1 above, and further in view of Takayuki et al. (Japanese Patent 61-73547).

1. In re claim 9, with reference to figure 1, Wilking ('217) discloses the claimed invention as applied to claim 1, except for a packaging pouch having a layer formed from polyacrylonitrile on the innermost side.

2. Takayuki et al. ('547) teaches an anti-inflammatory, analgesic drug packaging body formed by affixing a peel-off film configured from a polyacrylonitrile-based resin on the drug coated surface of a film-like anti-inflammatory, analgesic drug, and packaging and hermetically-sealing the same in a bag having an innermost layer of polyacrylonitrile-based resin which forms the innermost layer of the bag.

3. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the innermost layer of the packaging pouch (10) of Wilking ('217) to include a layer of polyacrylonitrile-based resin as taught by Takayuki et al. ('547) in order to keep moisture to a minimum within the package.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Watanabe et al. (US Patent 6,660,295), Yeager et al. (US Patent 5,938,012), and Yeager et al. (US Patent 6,119,855) all disclose a packaging pouch with a desiccant for absorbing moisture. Dick et al. (US Patent 6,689,197) discloses a sealing medium for composite packaging materials, in particular for packaging transdermal therapeutic systems with volatile active ingredients. Koch et al. (US Patent 6,955,842) discloses a desiccant composition containing moisture absorbing materials. Krampe et al. (US Patent 4,732,808), Pfister et al. (US Patent 5,232,702), and Shah et al. (US Patent 5,310,559) all disclose pressure sensitive skin adhesive sheet materials. Caggiano (US Patent 4,861,632) Discloses a laminated packaging material for packaging dry foods comprising a moisture resistant layer an absorbent layer and a perforated moisture resistant layer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNESTO A. GRANO whose telephone number is (571)270-3927. The examiner can normally be reached on 9:00am - 4:00pm Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Nguyen can be reached on 571-272-4491. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ernesto A Grano  
Examiner  
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/George Nguyen/  
Supervisory Patent Examiner, Art Unit 4147